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EXAMINER	
HSU, MARGARET H	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,269	IDEKER ET AL.	
	Examiner	Art Unit	
	Margaret Hsu	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/08/2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/29/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-46, drawn to a cardiac device that defibrillates and injects drugs and the methods to use the device, classified in class 607, subclass 3.

II. Claims 47-48, drawn to a drug injector that responds to arrhythmias, classified in class 604, subclass 891.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because in the subcombination of claim 47 the arrhythmia detector determines "if the subject is likely to experience an arrhythmia" (claim 47 line 3), whereas the detector in the combination, defibrillator with drug injection, only needs to determine if an arrhythmia is occurring not predict if it will occur (claim 12 line 3). The subcombination has separate utility as a cardiac drug injector.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Jarrett Abramson on 9/20/04 a provisional election was made with traverse to prosecute the invention of claim group I, claims 1-46. Affirmation of this election must be made by applicant in replying to this Office action. Claim 47-48 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. During a telephone conversation with Jarrett Abramson on 9/21/04 the examiner noted that the species claims containing internal and external, atrial and ventricular characteristics of the invention were not considered as patentably distinct. As such, if the examiner finds one of the inventions unpatentable over the prior art, the other invention will be considered an obvious variant under 35 U.S.C. 103(a).

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "92" and "94" have both been used to designate a

line connected to the injector and the lead 28 in Fig. 3; and 162 and 170 have both been used to designate the "synchronization monitor" depicted in Fig. 5.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 16, 51, 53 and 55.

9. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 110, 116, 133, 140, 142, 144, 145, 148, 163, 176, 178, 180, and 182.

10. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

11. The disclosure is objected to because of the following informalities: "and" in the last line of paragraph 53 seems like it should be "a."

Appropriate correction is required.

Claim Objections

12. Claims 16, 26,33, 38, and 46 are objected to because of the following informalities: the claims recite CaM Kinase as a calmodulin blocker. However in the similar Claim 4, the calmodulin blocker is CaM Kinase inhibitor. The inhibitor of a kinase protein does not do the same function as the kinase, but the opposite. Therefore for purposes in the rest of this action, claims 16, 26, 33, 38, and 46 are assumed to have "inhibitor" included after "CaM Kinase." Appropriate correction is required.

13. Claim 48 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 35. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

14. The examiner assumes that it was the applicant's intent to make claim 48 depend on claim 47, and as such claim 47 will be considered withdrawn from consideration as discussed in the restriction requirement.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 5, 6, 12-13, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Elsberry et al. (Pat No. 5,662,689).

17. In regards to claim 1, Elsberry et al. discloses a method of sensing an arrhythmia in need of cardioverting, applying a pain relieving therapy which in one embodiment is delivering an antiarrhythmic drug such as D-sotalol, procainamide, and quinidine (Col. 15 Line 23-29) that reduces the defibrillation threshold and then a cardioverting shock (Col. 26 lines 54- 67 and Col. 28 lines 47-55). Elsberry et al. discloses that administering the defibrillation threshold reducing agent such as D-sotalol, procainamide, and quinidine would allow a decreased amplitude, less painful cardioversion shock be applied to the patient (Col. 15 lines 28-29). Elsberry et al. also discloses injecting a calcium channel blocker (Col. 7 line 12) into the patient before or in conjunction with a defibrillation shock as an analgesic (Col. 5 line 39-42) to lessen the pain the patient experiences, and which inherently reduces the defibrillation threshold.

18. In regards to claim 5, Elsberry et al. discloses the invention is an atrial cardioverter (Col. 7 line 1).

19. In regards to claim 6, Elsberry et al. discloses the invention can also be a ventricular pacemaker/cardioverter/defibrillator (Col. 21 line 20).

20. In regards to claim 12, Elsberry et al. discloses in Fig. 1 a device that has an arrhythmia detector 70, a controller 62 (Col. 10 line 5), a drug injector 110 that

is able to deliver an antiarrhythmic drug into the heart (Col. 15 lines 38-41) and a shock generator 74 associated with the charge delivery controller 72, a part of the microcontroller 62.

21. In regards to claim 13, Elsberry et al. discloses that the controller has a set time programmed into the RAM/ROM to control the timing drug delivery with the shock (Col. 11 line 42-44) so that the amplitude of the defibrillation shock will be decreased (Col. 15, line 23-32).

22. In regards to claim 17, Elsberry et al. discloses that the device has an atrial fibrillation detector 70.

23. In regards to claim 18, Elsberry et al. discloses that in another embodiment of the device, a ventricular arrhythmia detector is included to detect ventricular fibrillation (Col. 15 line 64).

24. Claims 12, 14, 15, 19, 21-25, 27, 34, 35, 37, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Kroll et al. (Pat. No. 5,925,066).

25. In regards to claim 12, Kroll et al. discloses a cardiac device that detects atrial fibrillation (Col. 2 line 59) and a controller 14 that does the detecting (Col. Col. 4 lines 44-53) and control of a drug injecting catheter that delivers antiarrhythmic drugs (Col. 3 line 51-55) and pacing circuitry that can generate a therapeutic shock or several to the heart (Col. 3 line 67).

26. In regards to claim 14, Kroll et al. discloses that the cardiac device can administer amiodarone (Col. 3 line 59) and verapamil (Col. 3 line 63).

27. In regards to claim 15, Kroll et al. discloses the cardiac device can administer the antiarrhythmic drug ibutilide (Col. 3 line 60).

28. In regards to claim 19, Kroll et al. discloses that the cardiac device is an internal device (Col. 3 line 43).

29. In regards to claim 21, Kroll et al. disclose that the cardiac device delivers pacing pulses which are not above 34 Joules in strength because at strengths greater than 34 Joules the subject experiences considerable pain which is not considered pacing but cardioversion or defibrillation.

30. In regards to claim 22, Kroll et al. discloses a cardiac device that has a sensing electrode 10 positioned inside the heart (Col. 3 line 45), a battery 16, broadly referred to as a power supply, a controller 14 associated with the sensing electrodes through the amplifier 12, a plurality of electrodes 22 to deliver therapeutic electric shock to the heart, and a catheter 20 to deliver antiarrhythmic drugs.

31. In regards to claim 23, Kroll et al. discloses two sensing electrodes 10 in fig. 1 that are connected to a controller that distinguishes between an arrhythmia and fibrillation by the higher atrial rate detected through the atrial configuration of two sensing electrodes (Col. 3 line 45-46 and line 51-52).

32. In regards to claim 24, Kroll et al. discloses that the cardiac device can administer amiodarone (Col. 3 line 59) and verapamil (Col. 3 line 63).

33. In regards to claim 25, Kroll et al. also discloses the cardiac device can administer the antiarrhythmic drug ibutilide (Col. 3 line 60).

34. In regards to claim 27, Kroll et al. discloses the cardiac device is an internal device (Fig. 2).

35. In regards to claim 34, note similar rejection of limitations of claim 12 in paragraph 22 of this office action also Kroll et al. also discloses a drug pump in Fig. 2 which includes a second drug reservoir for the injection of a second antiarrhythmic drug (Col. 4 line 37-41).

36. In regards to claim 35, Kroll et al. discloses that the cardiac device can administer amiodarone (Col. 3 line 59) and verapamil (Col. 3 line 63).

37. In regards to claim 37, Kroll et al. discloses that the cardiac device can administer ibutilide (Col. 3 line 60) possibly as the 2nd arrhythmic drug.

38. In regards to claim 39, Kroll et al. discloses the cardiac device is an internal device (Fig. 2).

39. Claims 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Buscemi et al. (Pat. No. 5,690,682).

40. In regards to claim 41, Buscemi et al. discloses a system for treating an arrhythmia (Col 2 lines 8-13) that includes a processor 110 (Fig. 6) that detects an arrhythmia (Col. 5 lines 51-52), a defibrillation source, which is the analyzing means 30 that provides the pacing or defibrillation energy to the heart (Col. 5 line 52-53), a drug reservoir 34 that contains antiarrhythmic drugs (Col. 6 line 51-58) which is released before the shock with no specific delay (Col. 9 line 66 to Col. 10 line 4) and the microcomputer 110, synonymous with processor, controls the valve that controls amount of drug released (Col 6 lines 27- 28) and generates the electrical therapy to pace the heart (col. 5 line 54), the microcomputer 110, analog and digital circuits 116 and power supply 118 could also defibrillate

(implied in Col. 6 line 7), meaning the shock level is changeable from level necessary for pacing to a level necessary for defibrillation by the microcomputer.

41. In regards to claim 42 and 43, Buscemi et al. discloses the analyzing means 30 analyzes signals from the connecting means 32 that is connected to input connections 96, 98, 100 and to electrodes 70, 72 and 82 on the lead 16 which detect signals in both the right atria and the right ventricle (Col. 5 line 42-52), so it is possible the analyzing means 30 can detect an atrial and ventricular fibrillation event.

42. In regards to claim 44, Buscemi et al. discloses the device can administer chemicals such as amiodarone, verapamil and diltiazem in the invention (Col. 6 line 55-57).

43. In regards to claim 45, Buscemi et al. discloses the devices can administer chemicals such as dofetilide and ibutilide (Col. 6 line 56).

Claim Rejections - 35 USC § 103

44. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

45. Claims 2, 3, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al. (Pat. No. 5,662,689).

46. In regards to claim 2, Elsberry et al. discloses injecting a calcium channel blocker, which inherently could lower the defibrillation threshold and is an

analgesic, (Col. 7 lines 9-12) into the patient before a defibrillation shock (Col. 5 lines 48-60) but does not disclose expressly the use of particular calcium channel blocker drugs. It is well-known to administer calcium channel blockers as an antiarrhythmic drug for those suffering from arrhythmias and that calcium channel blockers such as Amlodipine, Bepridil, Diltiazem, Felodipine, Isradipine, Nicardipine, Nifedipine, Verapamil to help relieve chest pain or reduce pain. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method disclosed in Elsberry et al. with the usage of those particular calcium channel blockers which inherently decrease the fibrillation threshold, because the Applicant has not disclosed that a particular calcium channel blocker provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the antiarrhythmic drugs quinidine, d-sotalol, procainamide and calcium channel blockers as taught by Elsberry et al. because a physician may choose to administer one of the many antiarrhythmic drugs and calcium channel blockers which inherently lower the defibrillation threshold depending on the patient and situation. Therefore, it would have been an obvious matter of design choice to modify Elsberry et al. to obtain the invention as specified in claim 2.

47. In regards to claim 3, Elsberry et al. discloses injecting an antiarrhythmic drug to decrease the strength of the shock needed to defibrillate but does not disclose expressly the use of particular antiarrhythmic drugs listed in claim 3. It would have been an obvious matter of design choice to a person of ordinary skill

in the art to modify the method disclosed in Elsberry et al. with the usage of well-known antiarrhythmic drugs that lower the defibrillation threshold, because the Applicant has not disclosed that a particular antiarrhythmic drug of claim 3 provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the antiarrhythmic drugs quinidine, d-sotalol, procainamide as taught in Elsberry et al., because a physician may choose to administer one of the many antiarrhythmic drugs well known in the art to lower the defibrillation threshold depending on the patient and situation. Therefore, it would have been an obvious matter of design choice to modify Elsberry et al. to obtain the invention as specified in claim 3.

48. In regards to claim 7, Elsberry et al. discloses a method of applying an antiarrhythmic drug that reduces the defibrillation threshold to reduce the cardioversion shock needed but does not disclose expressly the strength of the shock needed. It would have been an obvious matter of design choice to a person of ordinary skill in the art to decrease the shock strength to less than 34 Joules in order to lessen the pain experienced by the subject, because the Applicant has not disclosed that a shock of less than 34 Joules provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Applicant's invention to perform equally well to lower defibrillation threshold with the atrial defibrillator that administers D-Sotalol as taught by Elsberry et al. because D-Sotalol is well-

known to lower defibrillation thresholds and defibrillation is routinely done with shocks less than 34 Joules especially in atrial defibrillation.

49. In regards to claim 8-10, Elsberry et al. discloses a method of applying an antiarrhythmic drug that reduces the defibrillation threshold to reduce the amplitude of a cardioversion shock needed but does not disclose expressly the amount of calcium channel blocker needed to achieve the percentage of reduction in shock, shock leading edge voltage, and shock energy. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify amount of calcium channel blocker administered to decrease defibrillation shock and characteristics of shock to achieve percent reductions in shock, shock energy and leading edge voltage, because the Applicant has not disclosed that amount of calcium channel blocker administered provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Applicant's invention to perform equally well to decrease the amplitude of the shock needed for cardioversion with an amount of antiarrhythmic drugs quinidine, d-sotalol, procainamide as taught in Elsberry et al., because the reduction in shock threshold would depend on the effectiveness of the particular drug employed and the conditions of the patient to determine the most effective drugs. It is well known that a wide variety of pulse parameters may be adjusted to lower the energy content of a shock, including the lowering of leading edge voltages to account for the reduced energy requirement afforded by the use of defibrillation threshold reducing drugs. Those of ordinary skill in the art bent on reducing the energy of the shock by introducing threshold reducing

drugs, would have therefore seen the obviousness of altering any signal parameter known to effect the energy content of a waveform including the leading edge voltage.

50. Claims 4, 11, 29, 30, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al. (Pat. No. 5,662,689) in view of Anderson et al. (Pat No. 6,518,245).

51. In regards to claim 4, Elsberry et al. discloses injecting an antiarrhythmic drug to decrease the strength of the shock needed to defibrillate but does not disclose the use of the calmodulin blocker CaM Kinase inhibitor as another antiarrhythmic drug that inherently also decreases the defibrillation threshold. Anderson et al. discloses a method of using CaM Kinase inhibitors, which is a calmodulin blocker, to treat arrhythmias (Col. 4 line 21-26) by intracoronary or intrapericardial delivery (Col. 8 line 25). Anderson et al. also discloses that CaM Kinase inhibitor can inhibit delayed afterpolarizations and intracellular calcium overload (Col. 4 lines 21-26) which inherently also reduces the defibrillation threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Elsberry et al. to include CaM Kinase inhibitor as another type of antiarrhythmic drug to treat arrhythmias by preventing intracellular overload therefore reducing the defibrillation threshold as taught by Anderson et al. since such a modification would provide more options of drugs to suit each patient or situation.

52. In regards to claim 11, Elsberry et al. discloses a method to reduce the amplitude of the cardioverting shock needed by applying an antiarrhythmic drug

that reduces the defibrillation threshold but does not disclose the use of an amount of calcium channel blocker effective inhibit an afterdepolarization and inherently would decrease the defibrillation threshold. Anderson et al. discloses using the drug ryanonide which blocks calcium from intracellular stores that prevents the intracellular calcium overload which underlie delayed afterdepolarizations (Col. 11 lines 42-48). Anderson et al. also discloses that ryanonide in 10μmole/l concentration is effective to prevent development of delayed afterdepolarizations. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method disclosed by Elsberry et al. with an amount of calcium channel blocker ryanonide as taught by Anderson et al. and as a result inhibit afterdepolarizations and decrease the fibrillation threshold since such a modification would provide another option of a drug to find the optimal drug for specific situations and patients.

53. In regards to claim 29, 32, and 33, Elsberry et al. discloses a method to reduce amplitude of a cardioversion shock needed by administering an antiarrhythmic drug like D-sotalol, which is the class of antiarrhythmic drugs that prolong refractory periods, and that reduces the defibrillation threshold but does not disclose administering a second antiarrhythmic drug. Anderson et al. teaches a method of administering an antiarrhythmic drug, a CaM Kinase inhibitor, which is a calmodulin blocker, in combination with antiarrhythmic drug of class III like D-Sotalol or dofetilide (Col. 9 lines 9-22). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method using one drug like D-Sotalol as taught by Elsberry et al. with a CaM Kinase

inhibitor as taught by Anderson et al. thereby inhibiting delayed afterdepolarizations and prolonging the refractory period. It would have been also been obvious to one having ordinary skill in the art at the time the invention was made to modify the method taught by Elsberry et al. with a CaM Kinase inhibitor and instead of D-sotalol, dofetilide of the same class of antiarrhythmic drugs as D-sotalol, as taught by Anderson et al. thereby inhibiting delayed afterdepolarizations and prolonging the refractory period, since either modification would increase the effectiveness of the antiarrhythmic agent to lower the defibrillation threshold and to treat arrhythmias.

54. In regards to claim 30, Elsberry et al. in view of Anderson et al. discloses injecting an antiarrhythmic drug a calmodulin blocker that treats delayed afterpolarizations or a calcium channel blocker that treats pain and inherently lowers the defibrillation threshold and injecting another antiarrhythmic drug that prolongs refractory periods therefore lowering the defibrillation threshold and shocking but does not disclose expressly the use of the particular calcium channel blocker drugs listed in the limitations of claim 30. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the method as taught by Elsberry et al. in view of Anderson et al. with the usage of any of the well-known calcium channel blockers that also inherently lower the defibrillation threshold, because the Applicant has not disclosed that a particular calcium channel blocker provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the

antiarrhythmic drugs quinidine, d-sotalol, procainamide, or calcium channel blocker analgesic that inherently lowers the defibrillation threshold as taught by Elsberry et al. or the calmodulin blocker CaM Kinase II with dofetilide as taught by Anderson et al. because a physician may choose to administer one of the many antiarrhythmic drugs well known in the art depending on the situation and patient. Therefore, it would have been an obvious matter of design choice to modify Elsberry et al. in view of Anderson et al. to obtain the invention as specified in claim 30.

55. In regards to claim 31, Elsberry et al. in view of Anderson et al. discloses injecting an antiarrhythmic drug to treat delayed afterpolarizations and injecting a drug to prolong refractory periods and shocking but does not disclose expressly the use but does not disclose the use of a particular antiarrhythmic drug of claim 31. Anderson et al. teaches using ryanodine to treat delayed afterdepolarizations (Col. 11 Lines 42-48) and prevent intracellular calcium overload as an effective antiarrhythmic agent. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Elsberry et al. to use ryanodine as one of the antiarrhythmic drugs injected that treats afterdepolarizations since such a modification would increase the effectiveness of the method.

56. Claims 16, 26, 38 are rejected under 35 U.S.C. 103(a) as obvious over Kroll et al. (Pat. No. 5,925,066) in view of Anderson et al. (Pat. No. 6,519,245). In regards to claim 16 and 26, Kroll et al. discloses a device with a detector with

sensing electrodes, controller, drug injector with a catheter, and pacing circuitry, (see rejection of similar limitations in the rejection of claim 12 and claim 22 in paragraphs 22 and 27) but does not disclose the use of the calmodulin blocker CaM Kinase inhibitor as an antiarrhythmic drug. Anderson et al. discloses CaM Kinase inhibitor can also help treat atrial arrhythmias (Anderson et al. Col 4 lines 3-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Kroll et al. to also administer CaM Kinase inhibitor as taught by Anderson et al. since such a modification would facilitate treating an atrial fibrillation.

57. In regards to claim 38, Kroll et al. discloses a atrial arrhythmia sensor and drug injector with pacing and with ability to inject two drugs (see similar rejection of limitations in claim 34) but does not disclose the injector administers calmodulin blocker CaM Kinase inhibitor as a therapeutic drug. Anderson et al. discloses CaM Kinase inhibitor can also help treat atrial arrhythmias (Anderson et al. Col 4 lines 3-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Kroll et al. to also administer a CaM Kinase inhibitor as taught by Anderson et al. since such a modification would facilitate treating an atrial fibrillation.

58. Claims 20, 28, 36, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al. (Pat. No. 5,925,066). In regards to claim 36, Kroll et al. discloses the invention but does not disclose expressly the use of particular antiarrhythmic drugs. It would have been an obvious matter of design choice to a

person of ordinary skill in the art to modify the device as taught by Kroll et al. with the usage of other well-known antiarrhythmic drugs, because the Applicant has not disclosed that a particular antiarrhythmic drug of claim 36 provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with any of the antiarrhythmic drugs as taught by Kroll et al., because a physician may choose to administer any one of the many antiarrhythmic drugs well known in the art depending on the patient and situation. Therefore, it would have been an obvious matter of design choice to modify Elsberry et al. to obtain the invention as specified in claim 36.

59. In regards to claims 20, 28 and 40, Kroll et al. discloses an implantable device. As discussed above in the restriction requirement (see paragraph 7), the examiner does not consider the species limitation "external" in claims 20, 28 and 40 to be patentably distinct from the limitation "internal" in 19, 27, and 39.

60. Claim 46 is rejected under 35 U.S.C. 103(a) as obvious over Buscemi et al. (Pat. No. 5,690,682) in view of Anderson et al. (Pat. No. 6,519,245). Buscemi et al. discloses a system for treating arrhythmias (see rejection of similar limitations in the rejection of claim 41) but does not disclose the use of the calmodulin blocker CaM Kinase inhibitor as an antiarrhythmic drug. Anderson et al. discloses CaM Kinase inhibitor can also help treat arrhythmias (Anderson et al. Col 4 lines 3-4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Buscemi

et al. to also possibly administer CaM Kinase inhibitor since such a modification provide another option of drug to treat arrhythmias that provides advantages of being more safe, having no drug interactions, etc to better help patient.

Conclusion

61. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

"Calcium Channel Blocking Agents (systemic)" *Medline Plus: Drug Information* http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202107.html, 03/26/2002 contains information about Calcium channel blocking agents and their use as analgesics and as antiarrhythmic drugs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Margaret Hsu whose telephone number is (703)305-0491. The examiner can normally be reached on 8AM-4:30PM Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703)308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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MH

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PRIMARY EXAMINER
10-1-04